APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED JANUARY 14, 2004

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

03-1155

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC CORPORATION, and BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

and

MEDINOL LTD.,

Plaintiff-Appellants.

v.

JOHNSON & JOHNSON, CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Defendants-Appellees.

DECIDED: January 14, 2004

Before CLEVENGER, BRYSON, and GAJARSA, *Circuit Judges.*

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CLEVENGER, *Circuit Judge.*

This suit was brought in the United States District Court for the District of Delaware by Scimed Life Systems, Inc. ("Scimed"), Boston Scientific Corporation, Boston Scientific Scimed, Inc., and Medinol, Ltd. ("Medinol") (collectively "plaintiffs"). The plaintiffs allege Johnson & Johnson, Cordis Corporation, and Johnson & Johnson Interventional Systems, Inc. (collectively "Cordis") infringed several patents owned by Medinol directed to balloon expandable stents. After a two-week trial, a jury returned a verdict finding only one of the asserted claims not invalid and infringed. The jury found Cordis did not infringe the remaining claims and that these claims would have been obvious to a person of ordinary skill in the art at the time they were filed with the United States Patent and Trademark Office ("PTO"). Medinol appeals the district court's denial of the plaintiffs' post-trial motions for judgment as a matter of law ("JMOL") and a new trial on the issues of infringement and validity of the remaining claims. *See Scimed Life Sys., Inc. v. Johnson & Johnson*, 225 F. Supp. 2d 422, 441 (D. Del. 2002). We *affirm.*

I

The build-up of fatty deposits in coronary arteries, known as atherosclerosis, can eventually block the flow of blood to the heart. *Id.* at 425. During the 1970s, physicians began treating atherosclerosis by inserting a balloon attached to a wire catheter into a constricted artery and inflating the balloon so as to compress the fatty deposits against the vessel wall, thereby enlarging the space through which blood could flow. *Id.* This procedure is commonly known as balloon

angioplasty. *Id.* Within a few months of this procedure, an artery would often become blocked again by the recurrence of fatty deposits in a process known as restenosis. *Id.*

Physicians utilize balloon expandable stents to minimize the incidence of restenosis. *Id.* A stent is a medical device much like a miniature scaffolding that physically holds open a diseased artery into which it is inserted. *Id.* Stents have two positions: closed and open. A stent is inserted into an artery by placing it on a balloon and snaking it into the desired location with a catheter. *Id.* When the balloon is inflated, the stent expands from the closed position to the open position, and it remains in the artery after the physician removes the balloon and catheter.

This appeal concerns three patents directed to balloon expandable stents owned by Medinol: U.S. Patent No. 5,733,303 (the "'303 patent") issued on March 31, 1998; U.S. Patent No. 5,843,120 (the "'120 patent") issued on December 1, 1998; U.S. Patent No. 5,972,018 (the "'018 patent") issued on October 26, 1999. The patents-in-suit are part of the same patent family and share the same drawings and substantially similar written descriptions. None of the parties disputes that the key date for the purposes of invalidity is July 28, 1994, the filing date of a priority document common to each of the patents-in-suit.

One object of the patents-in-suit is to provide a flexible stent. *See, e.g.*, '303 patent, col. 1, ll. 52-53. Another object is to minimize the tendency of expandable stents to shrink longitudinally during expansion. *See, e.g., id.* at col. 1, ll. 53-54. This property is known as compensation for

foreshortening. Foreshortening made prior art stents hard to place accurately in blood vessels and led to scraping of the arterial wall during expansion. The district court identified "continuous uniform scaffolding, and resistance to radial deformation and collapse upon expansion" as additional features of the stents disclosed in the patents-in-suit. *Id.* at 425.

The plaintiffs alleged Cordis infringed several claims of the patents-in-suit by selling the BX Velocity Stent, the Corinthian Stent, the Crown Stent, and the Mini-Crown Stent. The asserted claims included claim 6 of the '303 patent which is directed to:

> An expandable stent defining a longitudinal aperture, including: a plurality of flexible connected cells, each of said flexible cells comprising:
>
> a) a first member having a longitudinal component having a first end and a second end;
>
> b) a second member having a longitudinal component having a first end and a second end,
>
> c) a third member having a longitudinal component having a first end and a second end;

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d) a fourth member having a longitudinal component having a first end and a second end;

e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;

f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;

g) a first flexible compensating member or flexible link having a first end and a second end disposed between said first member and said third member, said first end of said first flexible compensating member or flexible link communicating with said second end of said first member and said second end of said first flexible compensating member or flexible link communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other;

h) a second flexible compensating member or flexible link having a first end and a

second end disposed between said second member and said fourth member, said first end of said second flexible compensating member or flexible link communicating with said second end of said second member and said second end of said second flexible compensating member or flexible link communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member or flexible links differentially extendable or compressible when said stent is bent in a curved direction away from the longitudinal axis of said aperture; and

i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating member or flexible links disposed so that as said stent is expanded the distance between said first and said second flexible compensating member or flexible links increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the

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> ends of said first and said second flexible compensating member or flexible links open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating member or flexible link and so as to increase said variable longitudinal distance between said first and said second ends of said second flexible compensating member or flexible link so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion.

'303 patent, col. 7, ll. 1-65. Cordis was also charged with infringement of claim 12 of the '303 patent which is directed to: "The stent of claim 6, wherein said cells define a uniform cellular structure." '303 patent, col. 8, ll. 18-19.

In addition, the plaintiffs charged Cordis with infringement of claims 35, 47, and 60 of the '018 patent, which, in seriatim, recite:

> 35. A flexible, expandable stent, comprising:
>
> a plurality of flexible cells provided with a plurality of first loops and a plurality of second loops, said first loops and said second loops disposed and adapted to cooperate so that upon

the expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

47. A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis including:

(a) a plurality of cells flexible around said longitudinal axis connected to one another about the circumference of said stent to form a band of flexible cells, each of said flexible cells having apices disposed apart and generally opposite to one another,

(b) each of said flexible cells having a plurality of flexible links disposed apart and generally opposite to one another,

(c) each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween, and

(d) said flexible cells in said adjacent bands of flexible cells connected to one another.

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60. A stent having a longitudinal axis formed of a tube having a patterned shape, the patterned shape comprising:

a. first meander patterns having axes extending in a first direction;

b. second meander patterns having axes extending in a second direction, different than said first direction, wherein said second meander patterns intersect with said first meander patterns;

c. wherein said first meander patterns have loops;

d. wherein said first meander patterns are spaced apart to leave a portion of said second meander patterns between each pair of adjacent first meander patterns;

e. wherein each of said second meander patterns has at least one loop between at least one pair of adjacent first meander patterns, and

f. wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of

> said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

'018 patent, col. 10, ll. 8-15; col. 12, ll. 24-40; col. 16, ll. 4-25.

Finally, the plaintiffs contended that Cordis infringed claim 13 of the '120 patent which recites:

> An expandable stent formed of an elongated cylindrical unitary tube suitable for insertion into a lumen or blood vessel in which it may be expanded, comprising: a plurality of first meanders extending in a first direction on the cylinder of the tube and a plurality of second meanders extending in a second direction, on the cylinder of the tube, wherein the first and second meanders are formed with loops and are interconnected such that at least one of the loops of each of the first meanders is disposed between each consecutive second meander to which the first meander is connected, and at least one of the loops of each of the second meanders is disposed between each consecutive first meander to which it is connected; the first and second meanders defining a plurality of enclosed spaces.

'120 patent, col. 7, ll. 13-26.

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During the proceedings below, the district court concluded that the accused stents sold by Cordis did not, as a matter of law, literally contain the "communicating with" limitation of claim 6 of the '303 patent. *Scimed Life Sys.*, 225 F. Supp. 2d at 432 n. 1. The district court held a trial in which a number of issues were put to the jury, including, infringement of claim 12 of the '303 patent under the doctrine of equivalents; literal and equivalent infringement of claims 35, 47, and 60 of the '018 patent; literal and equivalent infringement of claim 13 of the '120 patent; validity of the claims asserted against Cordis.

At the conclusion of the two-week trial, the jury returned a verdict finding only claim 13 of the '120 patent not invalid and literally infringed by Cordis's sale of the Corinthian Stent. *Id.* at 433. The jury determined Cordis did not infringe any of the asserted claims, literally or under the doctrine of equivalents, by selling the three remaining accused stents. *Id.* at 432-33. The jury also found the asserted claims of the '303 and '018 patents invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1 and for obviousness under 35 U.S.C. § 103(a). *Id.* at 432-34.

The plaintiffs subsequently moved for JMOL and for a new trial on the issues of infringement which the jury resolved adverse to them and on the issue of the validity of the asserted '303 and '018 patent claims. Applying the substantial evidence standard of review, the district court held that a reasonable jury could have concluded that the accused stents sold by Cordis do not contain, literally or by equivalence, several of the claim limitations found in the asserted claims of the '303 and '018 patents. *Id.* at 434-38. The district court

also held that the jury's written description determination was unsupported by substantial evidence, *id.* at 438-39, but concluded nevertheless that, "[t]he record reflect[ed] substantial evidence that support[ed] the jury's finding by clear and convincing evidence that the asserted claims of the '303 and '018 patents are invalid for obviousness over the prior art." *Id.* at 441. The district court denied the plaintiffs' motions accordingly. Of all the plaintiffs, only Medinol appealed the district court's decision to us. We have jurisdiction over Medinol's appeal pursuant to 28 U.S.C. § 1295(a)(1).

II

A

We review a denial of a motion for JMOL by reapplying the district court's standard of review. *See Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1318 (Fed. Cir. 2003) ("We review the grant or denial of JMOL without deference by reapplying the JMOL standard of the district court."). To prevail on appeal, the party that moved the district court for JMOL "must prove that the jury's factual findings were not supported by substantial evidence or that the facts were not sufficient to support the conclusions necessarily drawn by the jury on the way to its verdict[.]" *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 147 F.3d 1374, 1376 (Fed. Cir. 1998). "We review the trial court's denial of a motion for a new trial for abuse of discretion." *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1374 (Fed. Cir. 2003) (citing *Stryker Corp. v. Davol, Inc.*, 234 F.3d 1252, 1259 (Fed. Cir. 2000)).

Although Medinol has appealed those aspects of the district court's decision relating to infringement as well as validity, we do not address its contentions as to infringement because we hold there was substantial evidence in the record to support the conclusion that the asserted claims of the '303 and '018 patents were obvious over the prior art at the time they were filed with the PTO. "[O]bviousness is a question of law based on underlying facts[.]" *Med. Instrumentation and Diagnostics Corp. v. Elekta, AB*, 344 F.3d 1205, 1220 (Fed. Cir. 2003) (citation omitted). We review the ultimate determination of obviousness *de novo*. *See Akamai Techs. v. Cable & Wireless Internet Servs.*, 344 F.3d 1186, 1195 (Fed. Cir. 2003). When, as here, the obviousness issue is submitted to the jury, we presume "the jury resolved . . . underlying factual disputes in favor of the verdict winner and leave those presumed findings undisturbed if they are supported by substantial evidence." *See Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991) (reviewing jury determination on issue of obviousness) (citation omitted).

Claim interpretation is the first step of a validity analysis. *See Amazon.com, Inc. v. barnesandnoble.com, inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). The second step entails determining whether or not the prior art renders the properly construed claim obvious. *Id.* A claim is invalid if the differences between it and the prior art "are such that the [claimed] subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art[.]" 35 U.S.C. § 103(a) (2002); *Graham v. John Deere Co.*, 383 U.S. 1, 13 (1966). The legal

conclusion of obviousness is driven by several factual determinations, including, "(1) the scope and content of the prior art; (2) the differences between the prior art and the [properly construed] claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." *Riverwood Int'l Corp. v. Mead Corp.*, 212 F.3d 1365, 1366 (Fed. Cir. 2000) (quoting *Graham*, 383 U.S. at 13-14).

Even if all of the elements of a claim are present in the prior art, the claim will not be obvious unless the prior art also contained, at the time the claim was filed, a motivation to combine prior art elements into the claimed invention. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998) (upsetting jury verdict of obviousness because record lacked evidence of motivation to combine). The conclusion that the prior art contained a motivation to combine is a conclusion of fact. *See Med. Instrumentation and Diagnostics*, 344 F.3d at 1221 (citing *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000)). "The suggestion or motivation to combine references does not have to be stated expressly; rather it 'may be shown by reference to the prior art itself, to the nature of the problem solved by the claimed invention, or to the knowledge of one of ordinary skill in the art.'" *Id.* at 1221-22 (quoting *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 728 (Fed. Cir. 2002)).

C

Although Medinol argues the district court committed several errors of claim interpretation, only one of these alleged mistakes goes to the issue of validity. Medinol argues that the district court construed improperly the "uniform

cellular structure" limitation of claim 12 of the '303 patent, and as a result, that the jury's determinations regarding the differences between the prior art and the properly construed claims were unsupported by substantial evidence. The district court stated in its instructions to the jury that "uniform cellular structure" means "[t]he flexible connected cells of claim 6 have the same structure." (J.A. at 8735.) This definition is, verbatim, the definition the district court gave "uniform cellular structure" during *Markman* proceedings held before trial. Furthermore, it is nearly the exact definition Medinol proffered below in its Opening Brief on Claim Construction. Medinol proposed "uniform cellular structure" meant that "[a]ll of the cells of the stent have the same structure." (J.A. at 4535.) Although pressed on the issue at oral argument, counsel for Medinol was unable to explain exactly how the district court's construction of "uniform cellular structure" was inconsistent with the express words of claim 12. We do not perceive any error in the district court's construction of "uniform cellular structure" that warrants upsetting the district court's conclusion that claim 12 was invalid for obviousness.

D

During oral argument, counsel for Medinol conceded that the prior art contained each and every element of the asserted claims of the '303 and '018 patents at the time they were filed with the PTO. However, on rebuttal, counsel retreated from this position, and asserted the prior art did indeed lack a teaching of compensation for foreshortening, which is a requirement of each of the claims the district court held invalid. Medinol thereby called into question the existence

of substantial evidence of the presumed jury finding that compensation for foreshortening was present in the prior art.

Our review of the record indicates the jury was presented with substantial evidence of the existence of compensation for foreshortening in the prior art. Direct examination of Cordis's expert at trial, Dr. Nigel Buller, demonstrated as much. Dr. Buller first testified that stents made from a combination of rings (members) and flexible connectors (links), as required by the asserted claims of the '303 and '018 patents, were in the prior art. On direct examination, Dr. Buller was asked whether compensation for foreshortening was in the prior art and answered:

> Yes. It was an obvious result of combining one of these flexible connectors with the ring structure that was known to shrink. So any of these serpentine rings were known to shrink when they expand. And if you combine a flexible connector that can get bigger, then it is an obvious result that foreshortening will be compensated for.

(J.A. at 2825.) Dr. Buller proceeded to identify three prior art references disclosing stent designs that compensated for foreshortening. This testimony was substantial evidence for the jury to have found that the compensation for foreshortening element was present in the prior art at the time the claims asserted against Cordis were made.

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E

Medinol argues that even if each of the elements of the asserted claims was in the prior art, the record does not demonstrate there was a motivation to combine these elements in such a way that a person of ordinary skill would have arrived at the stents disclosed in the '303 and '018 patents. Again, we are not persuaded by Medinol's arguments. The record contains substantial evidence that a person of ordinary skill in the art, did, in fact, combine the elements of the stent design claimed by the '303 and '018 patents prior to July 28, 1994. As the district court recounted in its Memorandum Opinion in which it ruled on motions for summary judgment, in May 1994, Scimed engineers Paul Burmeister *et al.*, ("Burmeister") "evaluated the concept of a hybrid stent that would partially self-expand and then fully expand with a balloon." Burmeister filed a patent application with the PTO on May 19, 1994 that included several drawings and that was subsequently abandoned. At trial, Dr. Buller testified the Burmeister design contained the design aspects of the stents claimed in the '303 and '018 patents, including serpentine rings, flexible connectors, compensation for foreshortening and flexible cells.[1]

At oral argument, counsel for Medinol contended that the Burmeister application was not sufficient evidence of motivation to combine because it was ultimately abandoned.

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1. The district court held the drawings filed with the Burmeister application did not anticipate the asserted claims of the '303 and '018 patents as a matter of law because they were not publicly accessible, and therefore, were not prior art. This issue is not before us in this appeal.

Medinol believes Burmeister failed to realize the commercial success his stent would enjoy in the marketplace, and as a result, failed to conceive the full scope of the invention asclaimed in the '303 and '018 patents. At trial, Cordis elicited testimony from Dr. Buller that Burmeister was not trying to design a better stent *per se*, but rather, was experimenting with different metals from which an improved stent might be manufactured. Dr. Buller added that he believed Burmeister abandoned the application because a suitable metal for an improved stent could not be found and the design itself was obvious.

At bottom, the subjective reasons for abandonment are irrelevant to assessing the probative value of the Burmeister application on the issue of an existence in the prior art of a motivation to combine. The question "is what a hypothetical ordinarily skilled artisan would have gleaned from the [Burmeister application] at the time that the patent application leading to the ['303 and '018 patents] was filed." *Amazon.com*, 239 F.3d at 1364. That Burmeister may have improvidently given up attempts to secure patent protection for his design is irrelevant to the question of whether the knowledge of an ordinarily skilled artisan contained a motivation to combine the claim elements of the '303 and '018 patents that were present in the art prior to July 28, 1994. *See id.* (holding individual skilled artisan's personal failure to realize prior art elements could be combined based on actual knowledge was irrelevant to ultimate question of existence of motivation to combine). The jury had before it expert testimony that a person of ordinary skill in the art, on July 28, 1994, would inspect the drawings of the Burmeister application and conclude it disclosed a stent design that

combined the claimed elements of the balloon expandable stent design taught by the patents-in-suit. This was legally sufficient evidence from which the jury could have found a motivation to combine in the knowledge of one of ordinary skill in the art, a finding of fact we must presume the jury to have made given that it returned a verdict on the validity issue in favor of Cordis.

For the reasons stated above, and because we find Medinol's other arguments on the issue of obviousness unpersuasive, we affirm the district court's decision denying the plaintiffs' motions for JMOL. We also hold the district court did not abuse its discretion when it denied the plaintiffs' motion for a new trial.

APPENDIX B — MEMORANDUM OPINION AND JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED SEPTEMBER 27, 2002

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 99-904-SLR
(consolidated)

SCIMED LIFE SYSTENTS, INC., BOSTON SCIENTIFIC SCIMED, INC., BOSTON SCIENTIFIC CORPORATION and MEDINOL, LTD.,

Plaintiffs,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTENTS, INC.,

Defendants.

MEMORANDUM OPINION

Dated: September 27, 2002
Wilmington, Delaware

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s/ Sue L. Robinson
ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiffs Scimed Life Systents, Inc., Boston Scientific Scimed, Inc., Boston Scientific Corporation and Medinol, Ltd. filed this patent infringement action on December 20, 1999 against defendants Johnson & Johnson, Cordis Corporation and Johnson & Johnson Interventional Systents, Inc. Plaintiffs allege that defendants infringed certain claims of United States Patent Nos. 5,733,303 (the "'303 patent"), 5,843,120 (the "'120 patent"), and 5,972,018 (the "'018 patent") (collectively, the "Medinol patents"). Defendants seek a declaratory judgment that the asserted claims of the Medinol patents are invalid and not infringed by their BX Velocity, Crown, Mini-Crown and Corinthian stents. The court held a two-week jury trial on the issues of infringement and invalidity. Currently before the court are plaintiffs' motion for judgment as a matter of law and motion for a new trial.

II. BACKGROUND

A. The Technology

The dispute relates to balloon expandable stents. Balloon expandable stents and other types of stents are used to treat diseased blood vessels in the heart ("coronary arteries") and in other areas of the body ("peripheral arteries"). Coronary artery disease is caused by the buildup of fatty deposits on the inner lining of the coronary arteries. Known as atherosclerosis, this buildup narrows coronary arteries and

may eventually block the flow of blood to the heart. Untreated coronary disease can have serious consequences, including angina, heart attack or even death. Similar narrowing in arteries away from the heart causes problems for people with peripheral artery disease.

Until about twenty-five years ago, the primary treatment for coronary lesions was medication or coronary artery bypass graft surgery. In approximately 1975, physicians began to use a nonsurgical treatment called percutaneous transluminal coronary angioplasty, commonly known as "balloon angioplasty." During this procedure, a balloon attached to a wire catheter is snaked through a diseased artery until it reaches the site of blockage. A physician inflates the balloon, which compresses the fatty deposits against the vessel wall to open the artery and restore blood flow. The balloon and catheter are then removed from the body. Although balloon angioplasty represented a major advancement in combating artery disease, blood vessels often closed again within several months of the procedure. This recurrence of blockage is called "restenosis."

A stent improves the success of balloon angioplasty by minimizing the occurrence of restenosis. A stent is a small device that holds open an artery just like scaffolding inside a tunnel keeps the tunnel from collapsing. At issue in this case are balloon expandable stents which are used in conjunction with angioplasty balloons. The stent is placed on a balloon and inserted into an artery via a catheter. Once the balloon is at the area of blockage, it is inflated, which causes the stent to expand and press against the vessel wall, thereby opening the artery. The balloon is then deflated and removed, leaving the expanded stent in the artery to keep the vessel open and allow blood to flow.

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B. The Medinol Patents

The Medinol patents, invented by Henry Israel and Gregory Pinchasik and assigned to Medinol, claim certain flexible expandable stents. The Medinol patents share the same drawings and essentially the same specification, and are described as continuations of a series of applications beginning with Application Serial No. 282,181 (the '181 application"), filed on July 28, 1994, and continuations-in-part of Application Serial No. 213,272 (the "'272 application"), which was filed on March 17, 1994 and issued as United States Patent No. 5,449,373. The Medinol patents generally describe and illustrate stent designs that achieve the objectives of flexibility during delivery, compensation for foreshortening, continuous uniform scaffolding, and resistance to radial deformation and collapse upon expansion. Figure 8 of the Medinol patents is reproduced below. The stent displayed in Figure 8 is made up of a continuous network of uniform closed cells 50, each of which has opposing horizontal loops 63 and 65 and flexible links 67 and 71.

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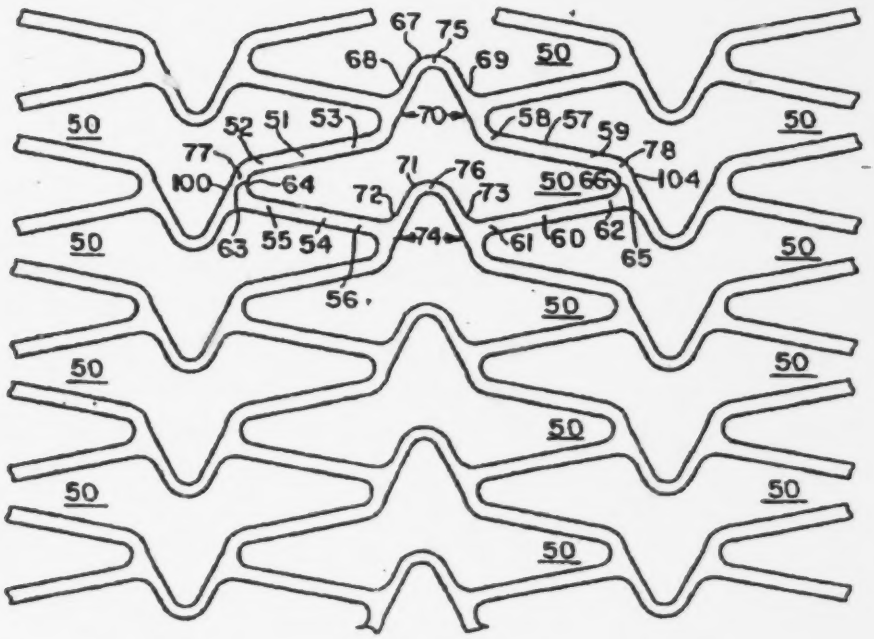

FIG. 8

1. The '303 Patent

The '303 patent issued on March 31, 1998 from Application Serial No. 457,354 (the "'354 application"), which was a continuation of the '181 application and a continuation-in-part of the '272 application. The claims of the '303 patent are directed to stents which have either: (1) flexible connected cells with a certain geometry or (2) meander patterns.

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Claim 12 of the '303 patent is a claim which is dependent on claim 6. The claims read:

> 6. An expandable stent defining a longitudinal aperture, including:
>
> a plurality of flexible connected cells, each of said flexible cells comprising:
>
> a) a first member having a longitudinal component having a first end and a second end;
>
> b) a second member having a longitudinal component having a first end and a second end;
>
> c) a third member having a longitudinal component having a first end and a second end;
>
> d) a fourth member having a longitudinal component having a first end and a second end;
>
> e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;
>
> f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;
>
> g) a first flexible compensating member or flexible link having a first end and a second end disposed between said first member and said third

member, said first end of said first flexible compensating member or flexible link communicating with said second end of said first member and said second end of said first flexible compensating member or flexible link communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other.

h) a second flexible compensating member or flexible link having a first end and a second end disposed between said second member and said fourth member, said first end of said second flexible compensating member or flexible link communicating with said second end of said second member and said second end of said second flexible compensating member or flexible link communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member or flexible links differentially extendable or compressible when said stent is bent in a curved direction away from the longitudinal axis of said aperture; and

i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating member or flexible links disposed

so that as said stent is expanded the distance between said first and said second flexible compensating member or flexible links increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the ends of said first and said second flexible compensating member or flexible links open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating member or flexible link and so as to increase said variable longitudinal distance between said first and said second ends of said second flexible compensating member or flexible link so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion.

12. The stent of claim 6, wherein said cells define a uniform cellular structure.

('303 patent, col. 7, lns. 1-65, col. 8, lns. 18-19)

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The court construed disputed terms of the '303 patent as follows:

(1) **"Stent."** A device, made of a body-compatible material, used to widen a blood vessel or other body opening (also called a "lumen"), and to maintain the resultant size of the blood vessel or lumen.

(2) **"Cell."** An arrangement of structural elements that defines an enclosed space.

(3) **"Member having a longitudinal component."** A "member" is a structural element that has its ends at different longitudinal positions with respect to the stent's longitudinal axis. A member's "longitudinal component" is the distance between the longitudinal positions of the first and second ends of the member.

(4) **"Loop."** A structural element that turns back on itself.

(5) **"First loop" and "second loop."** Horizontally-facing (or C-shaped) loops at the cell's two longitudinal ends.

(6) **"Disposed between."** Positioned in the space that separates structural elements.

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(7) **"Disposed generally opposite."** The first and second loops, defined as horizontally-facing structural elements, are positioned across from each other and approximately aligned with each other along the longitudinal axis of the stent.

(8) **"Flexible compensating member or flexible link."** A structural element that is flexible with respect to the stent's longitudinal axis and must be aligned along the longitudinal axis of the stent. A "flexible compensating member or flexible link" must connect adjacent cells, but the physical connection need not be made at points directly opposite each other.

(9) **"Communicating with."** To have a common part, to be connected, join.

(10) **"Said first and said second ends disposed a variable longitudinal distance from each other."** The flexible compensating member or flexible link is positioned so that, upon expansion of the stent, the distance between its two ends changes along the stent's longitudinal axis.

(11) **"Disposed . . . so as to substantially lessen the foreshortening of said stent upon its expansion."** This limitation encompasses an increase in the distance between the

longitudinal positions of the ends of the flexible compensating members or flexible links that is caused by expansion of the stent by a balloon or other mechanical means.

(12) **"Uniform cellular structure."** The flexible connected cells of claim 6 have the same structure.

(D.I. 256)

2. The '120 Patent

The '120 patent issued on December 1, 1998 from Application Serial No. 881,594, a continuation of Application Serial No. 783,467 (the "'467 application"), which was a continuation of the '354 application. The claims of the '120 patent are all directed to stents with meander patterns.

Claim 13 of the '120 patent reads:

13. An expandable stent formed of an elongated cylindrical unitary tube suitable for insertion into a lumen or blood vessel in which it may be expanded, comprising: a plurality of first meanders extending in a first direction on the cylinder of the tube and a plurality of second meanders extending in a second direction, on the cylinder of the tube, wherein the first and second meanders are formed with loops and are interconnected such that at least one of the loops of each of the first meanders is disposed between

> each consecutive second meander to which the first meander is connected, and at least one of the loops of each of the second meanders is disposed between each consecutive first meander to which it is connected; the first and second meanders defining a plurality of enclosed spaces.

('120 patent, col. 7, lns. 13-26)

The court construed disputed terms of the '120 patent as follows:

> **"Meander."** A periodic or repeating pattern of structural elements oriented about a center line. **"First meanders"** and **"second meanders"** identify and differentiate two different patterns.

(D.I. 256)

3. The '018 Patent

The '018 application issued on October 26, 1999 from Serial Application No. 026,999, which is a continuation of the '467 application. The claims of the '018 patent are directed to stents with meander patterns, cells or serpentine sections connected by flexible links. Claim 35 of the '018 patent reads:

> 35. A flexible, expandable stent, comprising:
>
> a plurality of flexible cells provided with a plurality of first loops and a plurality of second

loops, said first loops and said second loops disposed and adapted to cooperate so that upon the expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

('018 patent, col. 10, lns. 8-15)

Claim 47 of the '018 patent reads:

47. A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis including:

(a) a plurality of cells flexible around said longitudinal axis connected to one another about the circumference of said stent to form a band of flexible cells, each of said flexible cells having apices disposed apart and generally opposite to one another,

(b) each of said flexible cells having a plurality of flexible links disposed apart and generally opposite to one another,

(c) each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween, and

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(d) said flexible cells in said adjacent bands of flexible cells connected to one another.

('018 patent, col. 12, lns. 24-40)

Claim 60 of the '018 patent reads:

60. A stent having a longitudinal axis formed of a tube having a patterned shape, the patterned shape comprising:

a. first meander patterns having axes extending in a first direction;

b. second meander patterns having axes extending in a second direction, different than said first direction, wherein said second meander patterns intersect with said first meander patterns;

c. wherein said first meander patterns have loops;

d. wherein said first meander patterns are spaced apart to leave a portion of said second meander patterns between each pair of adjacent first meander patterns;

e. wherein each of said second meander patterns has at least one loop between at least one pair of adjacent first meander patterns; and

f. wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

('018 patent, col. 16, lns. 4-25)

The court construed disputed terms of the '018 patent as follows:

(1) **"A plurality of first loops and a plurality of second loops."** Two sets of loops.

(2) **"Disposed and adapted to cooperate so that upon expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

(3) **"Stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to**

said axis." The structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent.

(4) **"Apices."** Points at the two longitudinal ends of a cell of a stent.

(5) **"Plurality of flexible links."** Structural elements that serve to connect other structural elements but are themselves "disposed apart and generally opposite to one another."

(6) **"Each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween."** The flexible links are loops.

(7) **"Wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The loops disposed on the first meander patterns and the loops disposed on the second meander patterns must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops

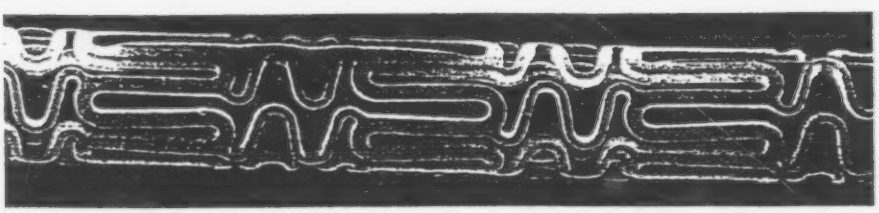
in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

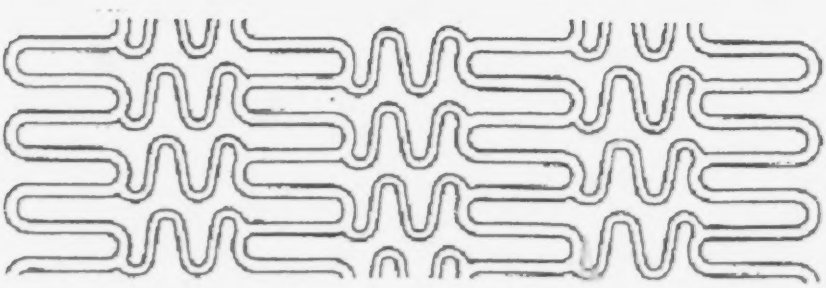
(D.I. 256)

C. The Accused Devices

1. BX Velocity Stent

Defendants' BX Velocity stent is composed of closed flexible cells, each of which has opposing horizontal loops connected by flexible N-shaped regions. When the BX Velocity stent is expanded, the "N-regions" lengthen to compensate for the shortening of the stent. A photograph and schematic of the BX Velocity stent are shown below.





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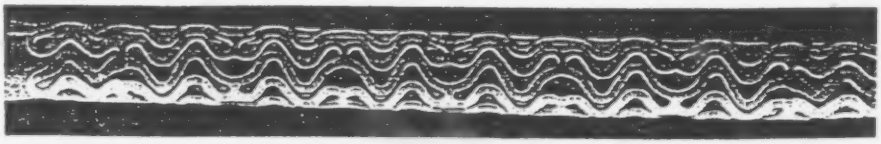
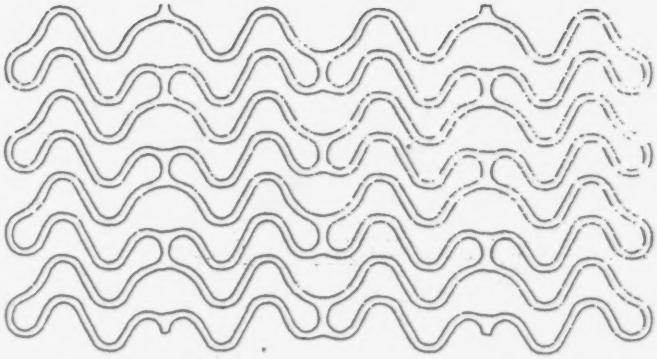
2. Crown and Mini-Crown Stents

Defendants' Crown and Mini-Crown stents are composed of a series of serpentine-ring structures which are fused together. A photograph and schematic of the Crown stent appear below.





The Mini-Crown is based on the design of the Crown stent, but is scaled to treat coronary arteries with a smaller diameter. Thus, the Mini-Crown has fewer rows than the Crown and is cut from a smaller and thinner-walled tube.

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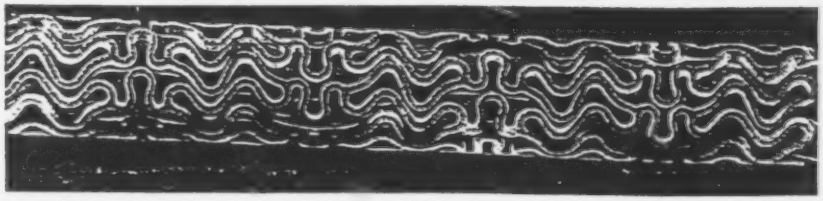
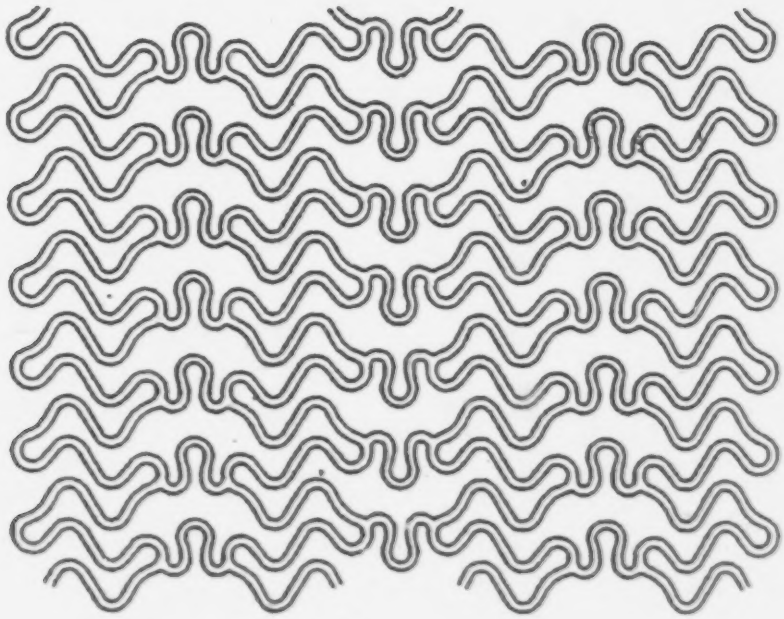
3. Corinthian Stent

Defendants' Corinthian stent has a similar structure to the Crown stent, but is larger and is used in the biliary systent and other peripheral arteries rather than in coronary vessels. A photograph and schematic of the Corinthian stent are reproduced below.





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Defendants are not challenging the jury's verdict regarding infringement by the Corinthian stent.

D. The Jury Verdict

On September 7, 2001, after a two-week trial, a jury returned the following verdict regarding the parties' claims of infringement and invalidity:

(1) BX Velocity Stent

(a) Claims 35, 47 and 60 of the '018 patent: no literal infringement; no infringement under the doctrine of equivalents; did not address the reverse doctrine of equivalents

(b) Claim 12 of the '303 patent: no infringement under the doctrine of equivalents[1]

(2) Crown and Mini-Crown Stents

(a) Claim 13 of the '120 patent: no literal infringement

(3) Corinthian Stent

(a) Claim 13 of the '120 patent: literal infringement

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1. The court previously found that the BX Velocity stent does not literally contain the "communicating with" limitation of claim 6 of the '303 patent. (D.I. 227) Thus, the BX Velocity stent cannot literally infringe claim 12, which depends from claim 6.

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The jury found all of the asserted claims invalid for both obviousness and failure to comply with the written description requirement except for claim 13 of the '120 patent, which the jury determined is valid. The jury also found that defendants' infringement was not willful, and awarded plaintiffs $7,021,728 based on a 9% royalty rate for defendants' sale of the Corinthian stent in the United States, and $1,279,556 based on a 7% royalty rate for defendants' foreign sales of the Corinthian stent manufactured in the United States. (D.I. 259)

III. STANDARDS OF REVIEW

A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.*, 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence

presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991); *Perkin-Elmer Corp.*, 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.*, 732 F.2d at 893. In sum, the court must determine whether the evidence reasonably supports the jury's verdict. *See Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998).

B. Motion for a New Trial

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

Fed. R. Civ. P. 59(a). The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. *See Allied Chem. Corp. v. Darflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem. Corp.*, 9 F.3d 282 (1993); *LifeScan Inc. v. Home Diagnostics, Inc.*, 103 F. Supp.2d 345, 350 (D. Del. 2000) (citations omitted). *See also* 9A Wright & Miller,

Federal Practice and Procedure § 2531 (2d ed. 1994) ("On a motion for new trial the court may consider the credibility of witnesses and the weight of the evidence."). Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. *See Zarow-Smith v. N.J. Transit Rail Operations*, 953 F. Supp. 581, 584-85 (D.N.J. 1997) (citations omitted). The court must proceed cautiously, mindful that it should not simply substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. Rather, the court should grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand. *See Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1352 (3d Cir. 1991); *EEOC v. State of Del. Dep't of Health and Soc. Servs.*, 865 F.2d 1408, 1413 (3d Cir. 1989).

IV. DISCUSSION[2]

A. Infringement by the BX Velocity Stent

A determination of infringement requires a two-step analysis. First, the court must construe the asserted claims so as to ascertain their meaning and scope. Second, the claims as construed are compared to the accused product. *See KCJ*

2. Plaintiffs challenge the court's construction of several limitations contained in the claims of the Medinol patents. The court went through the claim construction exercise prior to trial and declines to readdress its conclusions in this opinion.

Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1355 (Fed. Cir. 2000). Claim construction is a question of law while infringement is a question of fact. *See id.* To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). An accused product that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused product either literally or equivalently. *See Sextant Avionigue, S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 826 (Fed. Cir. 1999). An element in an accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. *KCJ Corp.*, 223 F.3d at 1359. A fact finder may also determine equivalence by assessing whether an element "does substantially the same thing in substantially the same way to get substantially the same result" as a claim limitation. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1260 (Fed. Cir. 1989) .

Occasionally, "the issue of literal infringement may be resolved with the step of claim construction, for upon correct claim construction, it may be apparent whether the accused device is within the claims." *Multiform Desiccants, Inc. v. Medzam*, 133 F.3d 1473, 1476 (Fed. Cir. 1998). Similarly, the determination of infringement under the doctrine of equivalents may be limited as a matter of law. Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquishes subject matter during the prosecution of the patent, either by amendment or argument. *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376-77 (Fed. Cir. 1999); *Dawn Equip.*, 140 F.3d at 1016.

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"Flexible Compensating Member or Flexible Link"

Plaintiffs argue that defendants misinterpreted the court's claim construction and prejudiced the trial when they characterized the N-regions of the BX Velocity stent as "diagonal." Prior to trial, the court construed the limitation "flexible compensating member or flexible link" to require that the element "be aligned along the longitudinal axis of the stent." (D.I. 228) The court also denied plaintiffs' motion for summary judgment of literal infringement and, in doing so, limited the range of equivalents of "flexible compensating member or flexible link" to exclude connectors that join non-adjacent cells.[3] (D.I. 227) At trial, defendants conceded that the BX Velocity stent's N-regions connected adjacent cells and, therefore, did not present the issue of prosecution history estoppel to the jury. Instead, defendants based their non-infringement argument solely on the court's claim construction — that the "flexible compensating member or flexible link" in claims 12 and 47 must be "aligned along the longitudinal axis of the stent."[4] At trial defendants

3. The court determined that plaintiffs surrendered all elements that connect non-adjacent cells when they distinguished United States Patent No. 5,102,417 during prosecution of the Medinol patents. (D.I. 227 at 7)

4. The Federal Circuit has emphasized the difference between claim construction and prosecution history estoppel:

> There is . . . a clear distinction between following the statements in the prosecution history in defining a claim term, and the doctrine of prosecution history estoppel,

(Cont'd)

presented the following testimony by Dr. Nigel Buller, defendants' medical expert:

> Q. Now let's take a look at the flexible link requirement. This, requires a flexible compensating member or flexible link, and the Court has given the following definition of flexible link: A structural element that is flexible with respect to the stent's longitudinal [axis] and must be aligned along the longitudinal [axis] of the stent. A flexible compensating member or flexible link must connect adjacent cells, but the physical connection need not be made at points directly

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(Cont'd)

> which limits expansion of the protection under the doctrine of equivalents when a claim has been distinguished over relevant prior art. Claim interpretation in view of the prosecution history is a preliminary step in determining literal infringement, while prosecution history estoppel applies as a limitation on the range of equivalents if, after the claims have been properly interpreted, no literal infringement has been found. The limit on the range of equivalents that may be accorded a claim due to prosecution history-estoppel is simply irrelevant to the interpretation of those claims.

Southwall Techs., 54 F.3d at 1578. Although defendants' application of the court's claim construction was not anticipated by either the court or plaintiffs, defendants crafted their non-infringement case on a legally-permissible basis. Thus, the court shall deny plaintiffs' motion for a new trial on the ground that defendants' "diagonal" arguments misled and confused the jury, resulting in inconsistent verdicts.

opposite each other. Does the diagonal connector of the BX Velocity constitute a flexible link under this definition?

A. No.

Q. Why not?

A. Because, quite simply, because it is not aligned along the longitudinal [axis] of the stent. The BX Velocity's connector runs diagonally or spirally and, therefore, is clearly not aligned with the longitudinal [axis] of the stent.

Q. How many requirements do you understand that the Court's definition imposes on the definition of flexible link?

A. Two.

Q. Which are they?

A. The first sentence and the second sentence.

Q. Does BX Velocity meet the definition of the first sentence?

A. No.

Q. Is it aligned along the long — is its connector aligned along the longitudinal [axis] of the stent?

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A. No. The connector is not aligned along the longitudinal [axis]. It runs diagonally or spirally.

(D.I. 271 at 1691-92) Thus, defendants presented sufficient evidence that the BX Velocity stent does not literally contain the "flexible compensating member or flexible link" limitation.

Dr. Buller also testified as to why the BX Velocity stent does not contain the "flexible compensating member or flexible link" limitation by equivalence:

Q. Now let's talk about the doctrine of equivalents. Do you have an opinion as to whether the flexibility connector or flexible link . . . of the BX Velocity, about whether or not it is substantially different from the structures disclosed in the patent and claim?

A. Yes. The spiral connectors of the BX Velocity are substantially different from the connectors shown in the patents.

Q. And why are they substantially different?

A. Because they are spirally oriented. They are diagonally or spirally oriented. By virtue of that they cause twisting, which was specifically excluded in the patents in the Cordis case.

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Q. What is the function of the flexible link or loop of Figure 7 which we're showing model the claims of the patent?

A. The function of the loop in the NIR stent or in this patent figure is to bring about flexibility in the stent without there being any twisting. And this is a generally longitudinal connector. It connects along points of alignment along the stent. Its function is flexibility, but it musn't bring about any twisting as a result.

Q. Does the connecting of the BX Velocity serve the same function?

A. No. It does not serve the same function. It serves an entirely different function by bringing about twisting and by virtue of this arrangement bringing about increased flexibility. It does it in an entirely different way. That is to say, that it brings about twisting of the stent as one of its features and it has an entirely different result.

Q. Do you have an opinion as to whether or not the flexible link or loop in the BX Velocity is a substantial change?

A. It is most certainly a substantial change. It is changing diagonal or helical connector, that has very many benefits as a result of this change to spiral orientation.

Q. Let me show you the design path again. Does this have any bearing in your analysis as to whether the diagonal connectors of the BX Velocity is a substantial change from the patents in suit?

A. Yes. In the patents in suit, there is a conventional generally longitudinal connector, which was conventional wisdom at the time. The design for the BX Velocity rejected this conventional wisdom and, instead, went towards a diagonal or spiral connector. It accepted the twisting and, indeed, found there were many features as a result of this and, indeed, the final design was for diagonal or spiral connectors that were all in alignment along the length of the stent.

(*Id.* at 1695-98)

The court concludes that defendants presented sufficient evidence for a reasonable jury to determine that the BX Velocity stent does not contain the "flexible compensating member or flexible link" limitation of claims 12 and 47 either literally or by equivalence, regardless of whether its N-regions connect adjacent cells.

2. "Communicating With"

The court also finds that there was sufficient evidence in the record to support a reasonable jury's conclusion that the BX Velocity stent does not contain the "communicating

with" limitation of claim 12 of the '303 patent by equivalence. Dr. Buller testified that the BX Velocity stent's connector

> communicates not with the third member at all but, in fact, with what you could label as the fourth member of the cell above. So once again, it is clearly showing that the connector in the BX Velocity stent is diagonally or spirally orientated. It goes from the first member of this cell to what is, in effect, the fourth member of the cell above and doesn't connect at all with the third member of the cell in question.

(*Id.* at 1690-91) Dr. Buller further explained that the function of the BX Velocity stent is substantially different than the function of the "communicating with" limitation, namely, that the BX Velocity stent used twisting to gain increased flexibility, whereas there is no twisting intended by the "communicating with" limitation of claim 12. (*Id.* at 1696-97) Thus, the jury could have arrived at its conclusion that the BX Velocity stent does not infringe claim 12 of the '303 patent by finding either that it does not contain the "flexible compensating member or flexible link" limitation or the "communicating with" limitation.

3. Compensation for Foreshortening

The court finds that defendants also presented sufficient evidence for a reasonable jury to conclude that the BX Velocity stent does not compensate for foreshortening as required by claims 35 and 60 of the '018 patent, i.e., that the connecting loop of claim 35 and the meander pattern of claim

60 are not "generally horizontal or longitudinal." At trial, Dr. Buller testified that the connectors of the BX Velocity stent "run diagonally or spirally" and function differently by causing twisting of the stent. (*Id.* at 1695-97) Because the jury could have found that the BX Velocity stent does not compensate for foreshortening either literally or by equivalence, the court concludes that the jury reasonably determined that the BX Velocity stent does not infringe claims 35 and 60 of the '018 patent.

4. "Substantially Uniformly Flexible"

Finally, the court finds that the jury could reasonably have determined that the BX Velocity stent does not infringe claim 47 of the '018 patent because it does not contain the "substantially uniformly flexible" limitation of claim 47 either literally or by equivalence. At trial, Dr. Buller gave the following testimony regarding claim 47:

> Q. Let me direct your attention to the substantially uniform requirement of Claim 47. Claim 47 also requires a stent which is substantially uniformly flexible with respect to its longitudinal [axis]. And the Court has defined this to say that the structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal [axis] of the stent.
>
> Does the BX Velocity infringe that claim element?
>
> A. No.

Q. Why not?

A. Because in the BX Velocity, the flexibility is very dominantly in the zone of flexible connectors. So moving along the stent as a whole, one first of all meets a relatively inflexible zone, followed by a very flexible zone and the flexible links, inflexible, very flexible, inflexible, very flexible. So all along the wave of the stent, the flexibility is in discrete bounds and isn't uniform along the stent

Q. Does the BX Velocity infringe the substantially uniform stent requirement of Claim 47?

A. No.

(*Id.* at 1693-94)

Thus, the jury could have found that the BX Velocity stent does not infringe claim 47 of the '018 patent because it does not contain the "flexible compensating member or flexible link" limitation or the "substantially uniformly flexible" limitation.

B. Infringement by the Crown and Mini-Crown Stents

The court concludes that substantial evidence supports the jury's verdict that the Crown and Mini-Crown stents do not infringe claim 13 of the '120 patent. Dr. Buller described the Crown stent as having "first meanders" that

run longitudinally along the length of stent and are simply connected at certain points. He testified that the Crown stent does not contain "second meanders" as required by claim 13, nor does it contain any "loops" between two sets of meanders, also required by the claim. (*Id.* at 1702-04) Although plaintiffs characterized the structure of the Crown stent differently, the jury was entitled to accept defendants' interpretation of the Crown and Mini-Crown stents. Thus, the court finds that the jury's verdict as to infringement by the Crown and Mini-Crown stents was supported by substantial evidence, and plaintiffs are not entitled to judgment as a matter of law on this issue.

C. Invalidity For Failure to Comply with the Written Description Requirement

Plaintiffs challenge the jury's verdict that the asserted claims of the '303 and '018 patents are invalid for failure to comply with the written description requirement of 35 U.S.C. 112, ¶ 1, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

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Patent claims are presumed valid. *See* 35 U.S.C. § 282. *See also Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1054 (Fed. Cir. 1989) ("The presumption of validity under 35 U.S.C. § 282 carries with it a presumption the examiner did his duty and knew what claims he was allowing."). To overcome this presumption, defendants were required to "provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention." *Biacore v. Thermo Bioanalysis Corp.*, 79 F. Supp.2d 422, 467 (D. Del. 1999), *aff'd per curiam*, Nos. 03-1337, 01-1446, 2002 WL 418166 (Fed. Cir. Mar. 15, 2002).

Defendants' evidence of invalidity of claims 12, 35, 47 and 60 for failure to comply with the written description requirement is essentially based on one exchange between defendants' counsel and Dr. Buller at trial:

> Q. One final point, Dr. Buller. I want to just briefly address what is called the written description requirement. Do you have an opinion as to whether the specification - let me state the requirement.
>
> The question I am going to ask you about is whether the specification of the patents in suit show that the inventor actually possessed what he claimed at the time of the invention.
>
> You understand that Medinol and Boston claim that the patents in suit include the diagonal connector of the BX Velocity. If that

> is so, do you have an opinion as to whether the specification of the patents in suit demonstrate that the inventor possessed such an invention?
>
> A. No. The inventor clearly didn't possess this invention. I think it is very clear from reading the patents that the inventor specifically excluded a diagonal or spiral connector, because of their very great concern about twisting. So not only did they not include this design within their patents, they very specifically excluded it and said, we are not interested in something that would cause twisting.

(D.I. 271 at 1724)

The court finds that defendants did not present clear and convincing evidence such that a reasonable jury could conclude that the claims are invalid for failure to comply with the written description requirement. The claims do not encompass a connector that connects non-adjacent cells (determined by the court during the prosecution history estoppel analysis), nor do they cover the "diagonal" connectors of the BX Velocity stent which function by twisting (determined by the jury during the infringement analysis). Defendants maintain that there is some "middle ground" where the claims are broader than the specification (which declares that the invention aims to avoid twisting) but not broad enough to encompass the BX Velocity stent. The court finds that defendants have failed to present clear

and convincing evidence of this "middle ground" at trial. Therefore, the court shall grant plaintiffs' motion for judgment as a matter of law as to the invalidity of claims 12, 35, 47 and 60 based on failure to comply with the written description requirement.

D. Invalidity for Obviousness

Plaintiffs move for judgment as a matter of law that the asserted claims of the '303 and '018 patents are not invalid for obviousness. To establish that a patent claim is obvious, it must be shown by clear and convincing evidence, that "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103(a). The question of obviousness turns on four factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicators of non-obviousness, such as commercial success. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996).

The existence of each limitation of a claim in the prior art does not, by itself, demonstrate obviousness. Instead, there must be a "reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success." *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1353 (Fed. Cir. 1999). "Such a suggestion or motivation may come from the references

themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved." *Id.* at 1356.

"The burden of showing, by clear and convincing evidence, the invalidity of patent claims is especially difficult when the prior art was before the PTO examiner during the prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990).

"Objective evidence of non-obviousness may be used to rebut a prima facie case of obviousness based on prior art references." *Tec Air, Inc. v. Denso Mfg. Mich, Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). In determining whether an invention is non-obvious, there are at least nine objective factors, i.e., "secondary considerations" that may be considered: (1) a long-felt and unmet need in the art for the invention; (2) failure of others to achieve the results of the invention; (3) commercial success of the invention; (4) copying of the invention by others in the field; (5) whether the invention was contrary to accepted wisdom of the prior art; (6) expression of disbelief or skepticism by those skilled in the art upon learning of the invention; (7) unexpected results; (8) praise of the invention by those in the field; and (9) independent invention by others. *See Graham*, 383 U.S. at 17-19; *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667-68 (Fed. Cir. 2000).

The court finds that defendants presented substantial evidence to support a reasonable jury's conclusion that claims 12, 35, 47 and 60 would have been obvious to one of ordinary skill in the art in July 1994, the time the inventions described in those claims were made.

Appendix B

First, defendants presented numerous prior art references available in July 1994 that disclosed key features of the inventions in the asserted claims of the '303 and '018 patents, namely, the use of serpentine rings to provide radial strength upon expansion (DX 6, 7, 8, 9, 18, 1172; D.I. 268 at 924-31; D.I. 270 at 1536-40, 1547-54; D.I. 271 at 1909-12, 1915), the use of flexible connectors to provide flexibility to the stent upon insertion (DX 8, 13, 36; PX 22; D.I. 268 at 945, 955-57; D.I. 270 at 1557-62, 1567-77, 1582-84), the use of flexible cells and multiple connectors to improve scaffolding (DX 8, 13, 18; PX 22; D.I. 270 at 1577-79, 1617-19; D.I. 271 at 1712), and compensation for foreshortening. (D.I. 271 at 1712, 1921)

Defendants then compared the prior art to the limitations of the claims and demonstrated that there was a motivation among those of ordinary skill in the art to place flexible, looped connectors between pairs of individual serpentine rings to maintain radial strength yet enhance flexibility. (DX 8, 13, 18, 36; PX 22; D.I. 268 at 956-65; D.I. 270 at 1557-62, 1567-77, 1582-84; D.I. 271 at 1710-12) Defendants also presented evidence that it would have been obvious for a person of ordinary skill in the art to increase the number of connectors around a stent to improve scaffolding. (DX 8, 13; PX 22; D.I. 270 at 1578-79; D.I. 271 at 1712) Specifically, defendants offered testimony that the necessary result of a combination of serpentine rings with looped connectors was that the rings would shorten longitudinally and the looped connectors would open to compensate for foreshortening, the feature upon which plaintiffs rested their non-obviousness argument at trial. (D.I. 268 at 1001-06; D.I. 269 at 1498-1501; D.I. 271 at 1712, 1921)

In addition, defendants demonstrated the lack of secondary considerations of non-obviousness, including the absence of a long-felt need for a stent that compensates for foreshortening (D.I. 267 at 649-53; D.I. 269 at 1476-78, 1498-1500), the success of the flexible Multi-Link stent, which is based on a patent that constitutes prior art to the Medinol patents (D.I. 266 at 621; D.I. 270 at 1546-51; DX 18), and independent invention of the stents encompassed by the asserted claims by others. (D.I. 271 at 1718-24; DX 12)

The record reflects substantial evidence that supports the jury's finding by clear and convincing' evidence that the asserted claims of the '303 and '018 patents are invalid for obviousness over the prior art. Thus, the court shall deny plaintiffs' motion for judgment as a matter of law on this ground.[5]

V. CONCLUSION.

For the reasons stated, plaintiffs' motion for judgment as a matter of law is granted in part and denied in part. Plaintiffs' motion for a new trial is denied. An appropriate order shall issue and judgment shall be entered accordingly.

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5. Plaintiffs' motion for a new trial based on an inconsistent jury verdict on obviousness is denied. Claim 13 of the '120 patent has an additional limitation, i.e., that the stent must have "at least one of the loops of each of the first meanders disposed between each consecutive second meander to which the first meander is connected" over claim 60 of the '018 patent. This supports the jury's verdict that claim 13 is not invalid for obviousness whereas claim 60 is invalid.

Appendix B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 99-904-SLR
(consolidated)

SCIMED LIFE SYSTENTS, INC., BOSTON SCIENTIFIC SCIMED, INC., BOSTON SCIENTIFIC CORPORATION and MEDINOL, LTD.,

Plaintiffs,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTENTS, INC.,

Defendants.

JUDGMENT IN A CIVIL CASE

Pursuant to the court's opinion and order dated September 27, 2002;

IT IS ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of defendants Johnson & Johnson, Cordis Corporation and Johnson & Johnson Interventional Systents, Inc. and against plaintiffs Scimed Life Systents; Inc., Boston Scientific Scimed, Inc., Boston Scientific Corporation and Medinol, Ltd. with respect to infringement of claim 12 of United States Patent

Appendix B

No. 5,733,303 (the "'303 patent") and claims 35, 47 and 60 of United States Patent No. 5,972,018 (the "'018 patent") by defendants' BX Velocity stent; infringement of claim 13 of United States Patent No. 5,843,120 (the "'120 patent") by defendants' Crown and Mini-Crown stents; and validity of claims 12 of the '303 patent and claims 35, 47 and 60 of the '018 patent.

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of plaintiffs Scimed Life Systents, Inc., Boston Scientific Scimed, Inc., Boston Scientific Corporation and Medinol, Ltd. and against defendants Johnson & Johnson, Cordis Corporation and Johnson & Johnson Interventional Systents, Inc. with respect to infringement of claim 13 of the '120 patent by defendants' Corinthian stent, and validity of claim 13 of the '120 patent.

s/ Sue L. Robinson
United States District Judge

Dated: September 27, 2002

s/ Francesca Tassone
(By) Deputy Clerk

APPENDIX C — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED AUGUST 15, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 99-904-SLR
(consolidated)

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC SCIMED, INC., BOSTON SCIENTIFIC CORPORATION and MEDINOL, LTD.,

Plaintiffs,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Defendants.

ORDER

At Wilmington this 15th day of August, 2001, having heard oral argument on the papers submitted in connection with claim construction issues; and having reviewed the patents' drawings, specifications and claims with a view to ascertaining the invention;[1]

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1. The '303, '120 and '018 patents share the same drawings and essentially the same specification.

Appendix C

IT IS ORDERED that the disputed claim language in the '303, '120 and '018 patents, as identified in the papers, shall be construed as follows, consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit:

1. **The '303 Patent – Claim 6**

a. **"Stent."** A device, made of a body-compatible material, used to widen a blood vessel or other body opening (also called a "lumen"), and to maintain the resultant size of the blood vessel or lumen. (Col. 1, lns. 13-17)

b. **"Cell."** An arrangement of structural elements that defines an enclosed space. (*Webster's Third New Int'l Dictionary* 359 (1993))

c. **"Member having a longitudinal component."** A "member" is a structural element that has its ends at different longitudinal positions with respect to the stent's longitudinal axis. A member's "longitudinal component" is the distance between the longitudinal positions of the first and second ends of the member. (Col. 4, ln. 66 to col. 5, ln. 6)

d. **"Loop."** A structural element that turns back on itself. (*Webster's* at 1335)

e. **"First loop" and "second loop."** Horizontally-facing (or C-shaped) loops at the cell's two longitudinal ends. (Col. 5, lns. 6-13)

Appendix C

f. **"Disposed between."** Positioned in the space that separates structural elements. (*Webster's* at 209)

g. **"Disposed generally opposite."** The first and second loops, defined as horizontally-facing structural elements, are positioned across from each other and approximately aligned with each other along the longitudinal axis of the stent. (Col. 5, lns. 6-13)

h. **"Flexible compensating member or flexible link."** A structural element that is flexible with respect to the stent's longitudinal axis and must be aligned along the longitudinal axis of the stent.[2] (Col. 5, lns. 13-31)

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2. The patents describe the invention as a stent designed to maximize longitudinal flexibility in the unexpanded state (*see, e.g.*, '303 patent, col. 3, lns. 38-45), and to minimize longitudinal foreshortening in the expanded state (*see, e.g.*, '303 patent, col. 1, lns. 52-54; col. 3, ln. 3 to col. 4, ln. 18). In order to accomplish these objectives, the patents describe the structural elements of the stent as being disposed to accommodate movement in two different and compensating directions, a generally vertical direction (*see, e.g.*, '303 patent, col. 2, ln. 63 to col. 3, ln. 2; col. 5, lns. 6-13) and a generally horizontal or longitudinal direction (*see, e.g.*, '303 patent, col. 3, lns. 3-7; col. 5, lns. 13-37). (*See also* D.I. 138, Ex. 3 at 00174) Further, the patents teach that the structural elements that accommodate movement in the longitudinal direction must be aligned along the longitudinal axis of the stent, as opposed to being diagonal, helical or spiral. (D.I. 137, Ex. 9 at 00059-60; D.I. 138, Ex. 3 at 00175-76) More specifically, the patentee distinguished the Palmaz '417 patent on the following grounds:

> Applicants have also amended Claim 1 to include the limitations of Claim 3 to indicate that the links

(Cont'd)

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i. **"Communicating with."** To have a common part, to be connected, join. (*Webster's* at 460)

j. **"Said first and said second ends disposed a variable longitudinal distance from each other."** The flexible compensating member or flexible link is positioned so that, upon expansion of the stent, the distance between its two ends changes along the stent's longitudinal axis. (Col. 5, lns. 38-62)

k. **"Disposed . . . so as to substantially lessen the foreshortening of said stent upon its expansion."** This limitation encompasses an increase in the distance between the longitudinal positions of the ends of the flexible

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(Cont'd)

> connect apices of adjacent cells of adjacent rigid segments. This is in contrast to Palmaz '417 and Cardon whose links are spiral-shaped and therefore, do not connect apices of adjacent segments. Instead, they connect the apex of a first cell on one segment with the apex of a second cell (of the second segment) which is shifted from the one which is adjacent to the first cell.

(D.I. 137, Ex. 9 at 00059-60) Based on this language, the court concludes that a flexible compensating member or flexible link must connect adjacent cells, but that neither the prosecution history nor the specification require that the physical connection be made at points directly opposite each other. Nor is there support in the prosecution history or specification for the added limitation suggested by defendants that the flexible compensating members or flexible links run parallel to each other (i.e., equidistant at all points) rather than merely lengthwise or in a longitudinal direction. *See, e.g., Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, No. 00-1454, 2001 WL 877575, at *11 (Fed. Cir. Aug. 6, 2001).

compensating members or flexible links that is caused by expansion of the stent by a balloon or other mechanical means.[3]

2. **The '303 Patent – Claim 8**

a. **"Area of inflection."** A portion of a stent element that is bent, i.e., a loop. (*Webster's* at 1160)

3. **The '303 Patent – Claim 12**

a. **"Uniform cellular structure."** The flexible connected cells of claim 6 have the same structure.

4. **The '120 Patent – Claim 13**

a. **"Meander."** A periodic or repeating pattern of structural elements oriented about a center line. (Col. 2, lns. 61-63) **"First meanders"** and **"second meanders"** identify and differentiate two different patterns. (Col. 2, ln. 61; col. 7, ln. 19)

5. **The '120 Patent – Claim 17**

a. **"Changes in the shape of the loops provides rigidity."** One of the meander patterns must have horizontally-facing loops which change shape upon expansion in order to provide rigidity to the stent. (Col. 4, lns. 28-30; col. 3, lns. 1-7)

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3. The court rejects defendants' suggestion that the structures of the stent must be capable of compensating for foreshortening without the aid of a balloon or other delivery device, as the use of a delivery device is clearly contemplated in the patent. (Col. 1, lns. 17-21)

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6. **The '018 Patent – Claim 35**

a. **"A plurality of first loops and a plurality of second loops."** Two sets of loops.[4]

b. **"Disposed and adapted to cooperate so that upon expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. (Col. 4, ln. 58 to col. 5, ln. 63) This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means. (Col. 1, lns. 17-21)

7. **The '018 Patent – Claim 39**

a. **"Said loops adapted so that said stent prior to expansion is substantially uniformly flexible along its longitudinal axis."** The first loops and second loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction, to provide substantially uniform flexibility to the

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4. Although the phrases "a first loop" and "a second loop" are used in the specification to describe the horizontally-facing (C-shaped) loops at either end of a cell (col. 5, lns. 7-14), the court finds that the phrases "first loops" and "second loops" should not be so limited, a conclusion supported by the fact that the function of minimizing foreshortening requires loops oriented in different directions.

unexpanded stent as one moves longitudinally along the stent.[5] (Col. 3, lns. 39-50; col. 5, lns. 35-39)

b. **"Said first loops and said second loops disposed and adapted to cooperate so that upon the expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

c. **"Said loops further adapted to impart rigidity."** At least some of the loops must be horizontally-facing loops which change shape to provide rigidity to the stent upon expansion. (Col. 4, lns. 23-26)

8. **The '018 Patent – Claim 47**

a. **"Stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis."** The structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent.

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5. Contrary to plaintiffs' interpretation, the phrase "substantially uniformly flexible" modifies the word "stent" in this claim, not the word "cells"; the cells must simply be flexible with respect to the longitudinal axis.

b. **"Apices."** Points at the two longitudinal ends of a cell of a stent. (*Webster's* at 99)

c. **"Plurality of flexible links."** Structural elements that serve to connect other structural elements but are themselves "disposed apart and generally opposite to one another." (*Webster's* at 1317; col. 12, lns. 33-35)

d. **"Each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween."** The flexible links are loops.

9. **The '018 Patent – Claim 60**

a. **"Wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The loops disposed on the first meander patterns and the loops disposed on the second meander patterns must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

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10. **The '018 Patent – Claim 63**

a. **"Wherein said stent is adapted so that when it is expanded radially, its overall length remains substantially the same because some elements of said stent grow in said tube's longitudinal direction while some elements of said stent shrink in said tube's longitudinal direction."** The stent must have structural elements oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one set of structural elements in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

s/ Sue L. Robinson
United States District Judge

APPENDIX D — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED AUGUST 15, 2001

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 99-904-SLR
(consolidated)

Dated: August 15, 2001
Wilmington, Delaware

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC SCIMED, INC., BOSTON SCIENTIFIC CORPORATION and MEDINOL, LTD.,

Plaintiffs,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION AND JOHNSON and JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Defendants.

MEMORANDUM OPINION

Dated: August 15, 2001
Wilmington, Delaware

s/ Sue L. Robinson
SUE L. ROBINSON, Chief Judge

Appendix D

I. INTRODUCTION

In this consolidated action, plaintiffs Scimed Life Systems, Inc. ("Scimed"), Boston Scientific Scimed, Inc. ("BSSI"), Boston Scientific Corporation ("BSC"), and Medinol, Ltd. ("Medinol") allege that defendants Johnson & Johnson ("J&J"), Cordis Corporation ("Cordis"), and Johnson & Johnson Interventional Systems, Inc. ("JJIS") willfully infringe and induce infringement of United States Patent Nos. 5,733,303 (the "'303 patent"), 5,843,120 (the "'120 patent"), and 5,972,018 (the "'018 patent") (collectively, the "Medinol patents"). The court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Currently before the court are various motions for summary judgment.[1] For the following reasons, the court shall deny plaintiffs' motion for summary judgment of literal infringement of the asserted claims of the '303 and '018 patents by the BX Velocity stent (D.I. 152), deny defendants' motion for summary judgment of non-infringement of claims 13 and 17 of the '120 patent by the Crown and Mini-Crown stents (D.I. 140), deny defendants' motion for summary judgment of non-infringement of the asserted claims of the Medinol patents by the BX Velocity stent (D.I. 146), grant plaintiffs' motion for summary judgment that the asserted claims of the Medinol patents are not anticipated by United States Patent No. 5,102,417 (the "'417 patent") (D.I. 154), deny as moot plaintiffs' motion for summary judgment that

1. Also pending before the court is defendants' motion for leave to file an amended answer and counterclaim. (D.I. 117) Defendants' motion is denied as untimely.

the asserted claims of the Medinol patents are not anticipated by United States Patent No. 5,449,373 (the "'373 patent") (D.I. 148), grant plaintiffs' motion for summary judgment that the stent designs in Figures 13, 14a and 14b of Application Serial No. 08/246,320 are not prior art (D.I. 150), and deny defendants' motion for summary judgment precluding lost profits damages for hypothetical United States sales of the NIR stent.[2] (D.I. 142)

II. BACKGROUND

The Medinol patents, invented by Henry Israel and Gregory Pinchasik and assigned to Medinol, claim certain flexible expandable stents. The Medinol patents share the same drawings and essentially the same specification, and are described as continuations of a series of applications beginning with Application Serial No. 282,181, filed on July 28, 1994, and continuations-in-part of Application Serial No. 213,272, which was filed on March 17, 1994 and issued as the '373 patent. Plaintiffs allege that defendants' BX Velocity, Crown, Mini-Crown and Corinthian stents infringe claims 6, 7, 8, 9, 10, 12 and 13 of the '303 patent, claims 13 and 17 of the '120 patent, and claims 35, 39, 47, 60 and 63 of the '018 patent.

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2. Defendants concede that if the court construes the asserted claims of the Medinol patents to disclaim the spiral or helical connectors of the '417 patent, then the '417 patent does not anticipate the Medinol patents. The court has adopted that construction and, therefore, plaintiffs' motion that the '417 patent does not anticipate the asserted claims is granted. Furthermore, defendants have agreed not to assert the '373 patent as an anticipatory reference, rendering plaintiffs' motion that the '373 patent does not anticipate the asserted claims moot.

Appendix D

A. The Burmeister Application

During May 1994, Scimed engineers Paul Burmeister, Brian Brown, Charles Eteneuer and Paul Fordenbacher ("Applicants") evaluated the concept of a hybrid stent that would partially self-expand and then fully expand with a balloon. Applicants filed for a patent on their invention on May 19, 1994 (the "Burmeister Application") that included several pages of drawings. (D.I. 156, Ex. M) Although Applicants indicated that they intended to send eighteen sheets of drawings, the Patent Office file reflects that only fifteen sheets were included. Those fifteen sheets contained Figures 1-10, 11b, 12 and 13, but not Figures 11a, 14a or 14b.[3] (*Id.*) On August 19, 1994, new drawings were submitted that also included Figures 11a, 14a and 14b. (*Id.*) On November 28, 1995, the Patent Office issued a Notice of Abandonment for Applicant's failure to respond to an April 26, 1995 Office Action.[4] (*Id.*) On May 18, 1995, Applicants filed an International PCT Application based on the Burmeister Application, but different drawings were substituted as Figures 13 and 14. The PCT Application was first published on November 30, 1995 and issued as European Patent Specification EP 0759730B1 on February 10, 1999. (D.I. 170, Ex. 49)

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3. Defendants contend that Applicants did include Figures 13, 14a and 14b in their May 19, 1994 submission, and the Patent Office later misplaced the drawings. (D.I. 167 at 12)

4. Plaintiffs contend that no further work was performed on Figures 13, 14a and 14b prior to the filing date of the Medinol patents which, for the purpose of the motion for summary judgment regarding the Burmeister Application, the parties agree is July 28, 1994. (D.I. 151 at 4)

Appendix D

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to

which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Infringement by Defendants' BX Velocity, Crown and Mini-Crown Stents

A determination of infringement requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993). "In order for a court to find infringement, the plaintiff must show the presence of every . . . [limitation] or its substantial equivalent in the accused device." *Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1199 (Fed. Cir. 1994). The determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). An infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents. *See id.* A finding of infringement under the doctrine of equivalents may be barred, however, if the patentee attempts to reclaim subject matter that it previously surrendered during prosecution. *See Hilgrave Corp. v. McAfee Assocs. Inc.*, 224 F.3d 1349, 1355 (Fed. Cir. 2000) ("[P]rosecution history estoppel bars recapture of subject matter surrendered during prosecution.").

Appendix D

The court finds that defendants' BX Velocity stent does not literally infringe claim 6 of the '303 patent. The "second end" of the BX Velocity's "first flexible compensating member or flexible link" does not "communicat[e] with" the "first end" of its "third member having a longitudinal component." ('303 patent, claim 6(g)) Similarly, the "first end" of the BX Velocity's "second flexible compensating member or flexible link" does not "communicat[e] with" the "second end" of its "second member having a longitudinal component." ('303 patent, claim 6(h)) The ends of these "flexible compensating members or flexible links" actually "communicat[e] with" the structural elements of other cells. ('303 patent, claim 6(e), (f)) Thus, because claims 7, 8, 9, 10, 12 and 13 ultimately depend on claim 6 of the '303 patent, the court concludes that defendants' BX Velocity stent does not literally infringe any of the asserted claims of the '303 patent. Plaintiffs are limited to alleging that the BX Velocity stent infringes those claims only by the doctrine of equivalents.[5]

The court also finds that there is a limited range of equivalents on the "flexible compensating member or flexible link" limitation of claim 6 of the '303 patent. Plaintiffs surrendered all diagonal, helical or spiral connector members when they distinguished the '417 patent during prosecution. (D.I. 137, Ex. 9 at 00059-60; D.I. 138, Ex. 3 at 00175-76) Consistent with the court's claim construction, therefore, plaintiffs are estopped from arguing that any diagonal, helical

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5. Because the jury may only find that the BX Velocity stent infringes the "communicating with" limitation by the doctrine of equivalents, the court will create a detailed verdict form, separating the limitations of claim 6 into individual questions.

or spiral element, i.e., a connector member that connects adjacent cells, is a "flexible compensating member or flexible link." With regard to the BX Velocity stent, the court concludes that there are genuine issues of material fact as to whether the "N-regions" of the stent infringe the "flexible compensating member or flexible link" limitation of claim 6 literally or by the doctrine of equivalents.

Finally, the court finds that there are genuine issues of material fact as to whether the BX Velocity, Crown or Mini-Crown stents infringe the asserted claims of the '120 patent, and whether the BX Velocity stent infringes the asserted claims of the '018 patent.

B. Figures 13, 14a and 14b of the Burmeister Application as Prior Art

Plaintiffs argue that Figures 13, 14a and 14b of the Burmeister Application are not prior art to the Medinol patents under 35 U.S.C. § 102(g), which states that an applicant is not entitled to a patent if

> before the applicant's invention thereof the invention was **made in this country by another who had not abandoned, suppressed, or concealed it**. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

(Emphasis added) Specifically, plaintiffs contend that although the Burmeister Application was arguably abandoned after the filing date of the Medinol patents, that abandonment vitiated the "constructive" reduction to practice created by the filing of the Burmeister Application. Thus, according to plaintiffs, the Burmeister invention was never "made" since it was never reduced to practice.[6] *See In re Costello,* 717 F.2d 1346, 1350 (Fed. Cir. 1983) ("[I]t has long been settled, and we continue to approve the rule, that an abandoned application, with which no subsequent application was copending, cannot be considered a constructive reduction to practice."). Defendants cite case law to the contrary, that an abandonment of an application must occur **prior** to the filing date of a patent in order to exclude that application as prior art pursuant to Section 102(g). *See Allen v. Brady,* 508 F.2d 64, 67 (7th Cir.1974) ("As we read the language [of Section 102(g)], the abandonment is irrelevant unless it occurred 'before the applicant's invention.' The use of the pluperfect tense—'had not abandoned'— plainly refers to an abandonment which occurred 'before the applicant's invention.'").

Although defendants present a respectable argument based on statutory interpretation, their position directly contradicts one of the fundamental principles of patent law—that prior art be available to the public. *See Kimberly-Clark Corp. v. Johnson & Johnson,* 745 F.2d 1437, 1453 (Fed. Cir. 1984) ("That is the real meaning of 'prior art' in legal theory—**it is knowledge that is available,** including what

6. The parties agree that Figures 13, 14a and 14b of the Burmeister Application were never **actually** reduced to practice. (D.I. 185 at 6)

would be obvious from it, at a given time, to a person of ordinary skill in an art.") (emphasis added). *See also Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) (stating that no patent should be granted which withdraws from the public domain technology already publicly available). The Burmeister Application was abandoned and the relevant drawings were never revealed to the public, nor were they actually reduced to practice. The only reason the drawings are at issue now is because Scimed, licensed by Medinol, is a party to this action and produced the drawings in discovery. In the absence of a voluntary publication of the Burmeister Application, the drawings never would have surfaced as potential prior art. Therefore, the court grants plaintiffs' motion for summary judgment that the stent designs in Figures 13, 14a and 14b of the Burmeister Application are not prior art.[7]

C. Recovery of Lost Profits on Hypothetical Sales of the NIR Stent

Defendants have moved to preclude plaintiffs from presenting any evidence on lost profits based on sales of the NIR stent, arguing that plaintiffs should not be permitted to assert that its NIR stent was properly on the market as a non-infringing product. Defendants base their argument on the jury verdict rendered against plaintiffs and in favor of defendants in *Cordis Corp. v. Boston Scientific Corp.*, No. 97-550-SLR (D. Del. verdict rendered on Dec. 11, 2000) (the "97-550 case").

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7. Moreover, adopting defendants' position would lead to the "anomalous" result of potentially depriving plaintiffs of their rights in the Medinol patents **because they developed their inventions too soon,** instead of after the abandonment of the Burmeister Application. *See* Donald Chisum, *Chisum on Patents* § 10.08[5] (2001).

The court concludes, however, that the jury verdict in the 97-550 case should not serve as an estoppel in this case. First, the issues tried in the 97-550 case are not the same issues that are going to be tried in the case at bar. Second, the adverse verdict is not a final one; given the possibility of the verdict being overturned in whole or in part on appeal, judicial economy suggests trying the case at bar on all issues. Finally, notions of equity support plaintiffs' position, that is, plaintiffs should not be precluded from presenting all issues just because defendants were the first to get to trial.

The court recognizes the complexities in these cases, but concludes that the case at bar should be tried without regard to the jury verdict returned in the 97-550 case. Therefore, defendants' motion for summary judgment precluding lost profits damages for hypothetical United States sales of the NIR stent is denied.

V. CONCLUSION

For the reasons stated, the court shall deny plaintiffs' motion for summary judgment of literal infringement of the asserted claims of the '303 and '018 patents by the BX Velocity stent, deny defendants' motion for summary judgment of non-infringement of claims 13 and 17 of the '120 patent by the Crown and Mini-Crown stents, deny defendants' motion for summary judgment of non-infringement of the asserted claims of the Medinol patents by the BX Velocity stent, grant plaintiffs' motion for summary judgment that the asserted claims of the Medinol patents are not anticipated by the '417 patent, deny as moot plaintiffs' motion for summary judgment that the asserted

claims of the Medinol patents are not anticipated by the '373 patent, grant plaintiffs' motion for summary judgment that the stent designs in Figures 13, 14a and 14b of the Burmeister Application are not prior art, deny defendants' motion for summary judgment precluding lost profits damages for hypothetical United States sales of the NIR stent, and deny defendants' motion for leave to file an amended answer and counterclaim. An appropriate order shall issue.

Appendix D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 99-904-SLR
(consolidated)

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC SCIMED, INC., BOSTON SCIENTIFIC CORPORATION and MEDINOL, LTD.,

Plaintiffs,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION AND JOHNSON and JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Defendants.

ORDER

At Wilmington, this 15th day of August, 2001, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Plaintiffs' motion for summary judgment of literal infringement of the asserted claims of the '303 and '018 patents by the BX Velocity stent (D.I. 152) is denied.

Appendix D

2. Defendants' motion for summary judgment of non-infringement of claims 13 and 17 of the '120 patent by the Crown and Mini-Crown stents (D.I. 140) is denied.

3. Defendants' motion for summary judgment of non-infringement of the asserted claims of the Medinol patents by the BX Velocity stent (D.I. 146) is denied.

4. Plaintiffs' motion for summary judgment that the asserted claims of the Medinol patents are not anticipated by the '417 patent (D.I. 154) is granted.

5. Plaintiffs' motion for summary judgment that the asserted claims of the Medinol patents are not anticipated by the '373 patent (D.I. 148) is denied as moot.

6. Plaintiffs' motion for summary judgment that the stent designs in Figures 13, 14a and 14b of Application Serial No. 08/246,320 are not prior art (D.I. 150) is granted.

7. Defendants' motions for summary judgment precluding lost profits damages for hypothetical United States sales of the NIR stent (D.I. 142) and for leave to file an amended answer and counterclaim (D.I. 117) are denied.

s/ Sue L. Robinson
United States District Judge

APPENDIX E — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING AND REHEARING EN BANC DATED AND FILED FEBRUARY 23, 2004

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

03-1155

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC CORPORATION, and BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

and

MEDINOL LTD.,

Plaintiff-Appellant,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Defendants-Appellees.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLANT, and the petition for rehearing having been referred to the panel that

heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on March 1, 2004.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: February 23, 2004